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APPENDIX G

510(K) Summary

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Predicate Device:

Transmedica: Digital Electronic Stethoscope
510(k) 963418
Product Code DQD
CFR section: ~~XXXX~~ 870.1875

Device Description

The Cardiovascular Sonospectrographic Analyzer (CSA) is a cardiovascular acoustic detection system. The CSA is a passive, non-invasive means of detecting, processing and displaying human physiologic acoustic data as an aide/adjunct to the clinician in diagnosing conditions. It is useable in all applications where clinicians have traditionally used the stethoscope. However, through the use of ultra-sensitive acoustic detection technology, digital signal processing and a Fast Fourier Transform (FFT), the CSA is able to detect, process and display physiologic acoustic signals from the human body that are as little as 1,000,000 times less than the peak acoustic energy level of a heart sound.

Intended Use

The Cardiovascular Sonospectrographic Analyzer (CSA) is intended for use in health care environments and setting where conventional stethoscopes (both electronically augmented and non-augmented) and phonocardiographs are used by health care professionals for the auscultation, graphical representation, measurement and archiving of cardiovascular, pulmonary, and other such sounds, both normal and abnormal, as produced by the human body. The CSA is a medical instrument intended for use by, or at the direction of, a qualified health care professional as a diagnostic aid for the clinical assessment and discrimination of acoustic patterns relating to or caused by clinically significant pathologies and medical conditions as known, defined, or specified in standard medical auscultation/phonocardiographic reference textbooks, peer review journals, and medically approved auscultation training materials. The CSA is further intended for the monitoring of interventional or prophylactic therapies that are

susceptible to the level of medical efficacy provided by CSA and as is clinically indicated at the discretion of the p physician. The CSA is also intended for use in telemedical applications where secondary analysis and options by non-local medical acoustic experts are indicated or desired.

Limitations on Intended Use: The CSA is not intended for use on a singular basis for delivery of health care, not as a standalone diagnostic aid for evaluation of cardiovascular conditions and pathologies for which other more suitable diagnostic tools or medical procedures are available or indicated.

Hardware Components
Medical cart with Uninterruptible Power Supply (UPS) See Figure 2.2.
IBM Compatible Computer, monitor, mouse, keyboard (See Figure 2.2)
Data Acquisition Module, I/O Tech DaqBoard 2000 series
Conditioning Electronics amplifier(See Figures 2.3 and 2.4)
Two physiological sensors (See Figure 2.5)
One environmental noise cancellation sensor (See Figure 2.6)
Audio reproduction
Headphone (optional)

Software Components:
- Data Recording Application (the DRA)
- Data Analysis Application (the DAA)

Performance Standards:

Electromagnetic Capability

PERFORMANCE TEST	APPLICABLE STANDARD
RF Emissions	CISPR-11/IEC-601-1-2 (modified) UL 2601
Magnetic Fields	RE101(mod) MIL-STD-461D
Electrostatic Discharges (Immunity)	IEC 801-2
Radiated EM Fields (Immunity)	IEC 601-1-2 (modified)
AC Voltage Fluctuations Trasients and Surges	Guidelines per Para. (M) (7) and sub-para.C (2)

Mechanical and Environmental

Performance Tests	Applicable Standard
Controls Protection	Company design specifications
Connector Protective	Company design specifications
Mechanical Safety	Company design specifications
Vibration and Shock Resistance	Company design specifications

Fluid Spill Resistance	IEC-601 (44.6) IEC 529
Temperature and Humidity	Company design specifications
Surface Temperature	Company design specifications
Toxic Materials	No toxic material from the device come into contact with the patient or operator during use

Similarities and Differences to Predicate Devices

The DES predicate device was developed in the 1990's based on basic technology and signal processing techniques well established in the scientific medical literature and in cleared auscultation and phonocardiography technology for the detection, processing, discrimination and display of the full range of cardiovascular sounds and murmurs. The DES development had required a design composed of the best features and properties of various phoncardiographic sensors for the purpose of detecting all of the physio-acoustic signals of interest and it also required novel digital signal processing and display software which utilized the well established and medically accepted Fast Fourier Transform technique as the basis for analyzing cardiovascular sounds and murmurs for their spectral content. However the DES was deficient as a viable medical device due to the requirement for operator training in the integral spectral analysis field and the time consuming visual analysis of the spectral signals and the manual measurement and calculations of the signals to discriminate the clinical information contained therein.

SonoMedica, Inc. acquired all rights to the DES predicate device and its original USFDA clearance and commenced a product development effort to reduce the original DES into a viable medical product. This development caused some minor refinements in the data acquisition circuitry but focused primarily upon developing software that automated the time intensive process of analyzing the detected cardiovascular signals in order to present the derived data in an easily accessible and understandable graphical format for ease and rapidity of use by the clinician or other medical user. The CSA hardware is essentially the same as was used and cleared in the predicate device. The CSA software is fully equivalent to the DES software in the CSA simply automates the analysis process as was required by the DES predicate device. The CSA use the Fast Fourier Transform as was used in the DES for signal decomposition as well as all of the same basic displays. The CSA employs features in some of its displays which are improvements upon the DES and the software is much more processing efficient due to its use of improved programming techniques but it is still all based on the same Visual Basic language as was used in the DES. In fact, the clinical data acquired by the DES is 100% compatible with the CSA and data acquired by the CSA is fully backwards compatible and can be processed and analyzed using the DES software.

Conclusion

As the CSA hardware is essentially the same as the DES predicate device; the basic digital signal processing techniques and displays being equivalent; both devices are based on the same software language; and the full backwards and forward compatibility of the recorded cardiovascular physio-acoustic data, it is concluded that the Cardiovascular Sonospectrographic Analyzer (CSA) is substantially equivalent to the DES predicate device from which is derived. The CSA does not use any form of radiation, contains no physical properties or features that present a risk, use no chemicals and has no design elements that also manifest a risk, it is further concluded that it is safe and effective for its intended use.